HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use INFUVITE PEDIATRIC safely and effectively. See full prescribing information for INFUVITE PEDIATRIC.

INFUVITE PEDIATRIC (multiple vitamins injection), for intravenous use
Initial U.S. Approval: 2004

INDICATIONS AND USAGE

INFUVITE PEDIATRIC is a combination of vitamins indicated for the prevention of vitamin deficiency in pediatric patients up to 11 years of age receiving parenteral nutrition (1)

DOSAGE AND ADMINISTRATION

- INFUVITE PEDIATRIC is a combination product that contains the following vitamins: ascorbic acid, vitamin A, vitamin D, thiamine, riboflavin, pyridoxine, niacinamide, dexpanthenol, vitamin E, vitamin K1, folic acid, biotin, and vitamin B12 (2.1, 2.2)
- **PHARMACY BULK PACKAGE**: Dispense single doses to many patients in a pharmacy admixture program. Use within 4 hours of puncture (2.1)
- Transfer contents of Vial 2 to contents of Vial 1. Then, take 1.5 mL, 3.25 mL, or 5 mL from mixture and add to at least 100 mL of intravenous dextrose or saline solution prior to intravenous use (2.3)
- After dilution in an intravenous infusion, refrigerate resulting solution unless used immediately. Use solution within 24 hours after dilution (2.3)
- Recommended daily dosage is based on patient's actual weight (2.2):
  - ***Weight < 1 kg:*** 1.5 mL of combined content of Vials 1 and 2
  - ***Weight ≥ 1 kg and < 3 kg:*** 3.25 mL of combined content of Vials 1 and 2
  - ***Weight ≥ 3 kg:*** 5 mL of combined content of Vials 1 and 2.
- Supplemental vitamin A may be required for low-birth weight infants (2.2)
- Monitor blood vitamin concentrations (2.4)
- See Full Prescribing Information for drug incompatibilities (2.5).

DOSAGE FORMS AND STRENGTHS

Injection: Vial 1 (40 mL fill in 50 mL Vial) and Vial 2 (10 mL). See Full Prescribing Information for vitamin strengths (3, 11)

CONTRAINDICATIONS

- Hypersensitivity to any of vitamins or excipients (4)
- Existing hypervitaminosis (4)

WARNINGS AND PRECAUTIONS

- *Risk of Aluminum Toxicity:* For at risk patients (renal failure or those with prolonged therapy), consider periodic monitoring of aluminum levels (5.1)
- *Allergic Reactions:* to thiamine may occur (5.2)
- *Hypervitaminosis A*: Patients with renal failure or liver disease may be at higher risk (5.3)
- *Vitamin K Antagonizes Warfarin's Anticoagulant Action:* Monitor INR (5.4, 7.2)
- *Interferes with Megaloblastic Anemia Diagnosis:* Avoid during testing for this disorder (5.5)
- *Risk of Vitamin Deficiencies or Excesses:* Monitor blood vitamin concentrations (5.6)
- *False Negative Urine Glucose Tests:* due to vitamin C (5.7)
- *Risk of Vitamin E Toxicity:* Additional oral and parenteral vitamin E may result in elevated vitamin E blood concentrations in infants (5.8)
- *Low Vitamin A Levels:* Monitor vitamin A levels (5.9)
- *Risk of E-Ferol Syndrome:* due to polysorbates (5.10)

ADVERSE REACTIONS

Adverse reactions have included anaphylaxis, rash, erythema, pruritis, headache, dizziness, agitation, anxiety, diplopia (6)

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Drug Interactions Affecting Co-administered Drugs:

- *Antibiotics:* Thiamine, riboflavin, pyridoxine, niacinamide, and ascorbic acid decrease activities of erythromycin, kanamycin, streptomycin, doxycycline, and lincomycin (7.1)
- *Bleomycin:* Ascorbic acid and riboflavin may reduce the activity of bleomycin (7.1)
- *Levodopa:* Pyridoxine may decrease blood levels of levodopa and levodopa efficacy may decrease (7.1)
- *Phenytoin:* Folic acid may decrease phenytoin blood levels and increase risk of seizure activity (7.1)
- *Methotrexate:* Folic acid may decrease response to methotrexate (7.1)

Drug Interactions Affecting Vitamin Levels:

- *Hydralazine, Isoniazid:* Concomitant administration of hydralazine or isoniazid may increase pyridoxine requirements (7.2).
- *Phenytoin:* May decrease folic acid concentrations (7.2)

USE IN SPECIFIC POPULATIONS

- *Renal Impairment:* Monitor renal function, calcium, phosphorus and vitamin A levels (8.6)
- *Hepatic Impairment:* Monitor vitamin A levels (8.7)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 07/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
2.1 Important Dosage and Administration Instructions
2.2 Dosage Information
2.3 Preparation and Administration Instructions
2.4 Monitoring Vitamin Blood Levels
2.5 Drug Incompatibilities
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Aluminum Toxicity
5.2 Allergic Reactions to Thiamine
5.3. Hypervitaminosis A
5.4 Vitamin K Antagonizes the Anticoagulant Action of Warfarin
5.5 Interferes with Diagnosis of Megaloblastic Anemia
5.6 Potential to Develop Vitamin Deficiencies or Excesses
5.7 Interference with Urine Glucose Testing
5.8 Vitamin E Overdose in Infants Receiving Additional Vitamin E
5.9 Risk of Low Vitamin A Levels
5.10 Risk of E-Ferol Syndrome in Low-Birth Weight Infants
6 ADVERSE REACTIONS
7 DRUG INTERACTIONS
7.1 Drug Interactions Affecting Co-administered Drugs
7.2 Drug Interactions Affecting Vitamin Levels
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.3 Nursing Mothers
8.4 Pediatric Use
8.6 Renal Impairment
8.7 Hepatic Impairment
10 OVERDOSAGE
11 DESCRIPTION
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

INFUVITE PEDIATRIC is a combination of vitamins indicated for the prevention of vitamin deficiency in pediatric patients up to 11 years of age receiving parenteral nutrition.

The physician should not await the development of clinical signs of vitamin deficiency before initiating vitamin therapy.

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosage and Administration Instructions

INFUVITE PEDIATRIC is a combination product that contains the following vitamins: ascorbic acid, vitamin A, vitamin D, thiamine, riboflavin, pyridoxine, niacinamide, dexpanthenol, vitamin E, vitamin K1, folic acid, biotin, and vitamin B12 *[see Dosage and Administration (2.2)]*.

INFUVITE PEDIATRIC is supplied as a pharmacy bulk package, and consists of two pharmacy bulk vials which must be combined and diluted prior to intravenous administration *[see Dosage and Administration (2.3)]*. As a pharmacy bulk vial, INFUVITE PEDIATRIC is intended for dispensing of single doses to many patients in a pharmacy admixture program and is restricted to the preparation of admixtures for infusion. Each closure shall be penetrated only one time with a suitable sterile transfer device or dispensing set that allows measured dispensing of the contents. INFUVITE PEDIATRIC is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).

Dispensing from a pharmacy bulk vial should be completed within 4 hours after the vial is penetrated. After combining contents of the two vials, a specified volume of INFUVITE PEDIATRIC is added to intravenous fluids prior to intravenous administration *[see Dosage and Administration (2.3)]*. Do not administer INFUVITE PEDIATRIC as a direct, undiluted intravenous injection as it may cause dizziness, faintness, and possible tissue irritation.

2.2 Dosage Information

The recommended daily dosage volume of 1.5 mL, 3.25 mL, or 5 mL of the combined contents of Vials 1 and 2 is based on the patient's actual weight of less than 1 kg, 1 kg to less than 3 kg, and more than or equal to 3 kg, respectively (see Table 1). One daily dose of combined content of vials 1 and 2 (1.5 mL, 3.25 mL or 5 mL) is then added directly to the intravenous fluid *[see Dosage and Administration (2.3)]*. Patients with multiple vitamin deficiencies or with increased vitamin requirements may need multiple daily dosages as indicated or additional doses of individual vitamins. However, additional daily dosages in infants are not recommended *[see Warnings and Precautions (5.8)]*. Supplemental vitamin A may be required for low-birth weight infants.

Table 1: Recommended Weight-Based Dosage of INFUVITE PEDIATRIC

	Less than 1 kg	**≥ 1 kg and < 3 kg**	**More than or equal to 3 kg**
Daily Dosage Volume	1.5 mL	3.25 mL	5 mL
Ascorbic acid (Vitamin C)	24 mg	52 mg	80 mg
Vitamin A (as palmitate)	690 IU (equals 0.2 mg)	1495 IU (equals 0.5 mg)	2,300 IU (equals 0.7 mg)
Vitamin D_3 (cholecalciferol)	120 IU (equals 3 mcg)	260 IU (equals 7 mc*g)*	400 IU (equals 10 mcg)
Thiamine (Vitamin B_1) (as the hydrochloride)	0.4 mg	0.8 mg	1.2 mg
Riboflavin (Vitamin B_2) (as riboflavin 5-phosphate sodium)	0.4 mg	0.9 mg	1.4 mg
Pyridoxine HCl (Vitamin B_6)	0.3 mg	0.7 mg	1 mg
Niacinamide	5.1 mg	11.1 mg	17 mg
Dexpanthenol (as *d*-pantothenyl alcohol)	1.5 mg	3.3 mg	5 mg

Vitamin E (*dl*-α-tocopheryl acetate)	2.1 IU (equals 2 mg)	4.6 IU (equals 5 mg)	7 IU (equals 7 mg)
Vitamin K_1	0.1 mg	0.1 mg	0.2 mg
Folic acid	42 mcg	91 mcg	140 mcg
Biotin	6 mcg	13 mcg	20 mcg
Vitamin B12 (cyanocobalamin)	0.3 mcg	0.7 mcg	1 mcg

2.3 Preparation and Administration Instructions

INFUVITE PEDIATRIC is supplied as a pharmacy bulk package. It consists of two pharmacy bulk vials that must be combined and diluted prior to intravenous administration.

(a) Transfer the contents of Vial 2 (10 mL of solution) into the contents of Vial 1 (40 mL of solution). The mixed solution (50 mL) will provide thirty-three 1.5 mL single doses, fifteen 3.25 mL single doses or ten 5 mL single doses.

(b) Add one dose directly to at least 100 mL of intravenous dextrose or saline solution for each patient. INFUVITE PEDIATRIC must be diluted in an intravenous infusion; it is not intended for direct infusion.

(c) Visually inspect for particulate matter and discoloration prior to administration.

(d) After puncture, complete dispensing from the pharmacy bulk vial should be completed within 4 hours.

(e) After INFUVITE PEDIATRIC is diluted in an intravenous infusion, refrigerate the resulting solution unless it is to be used immediately, and use the solution within 24 hours after dilution.

(f) Minimize exposure to light because some of the vitamins in INFUVITE PEDIATRIC, particularly A, D and riboflavin, are light sensitive.

(g) Discard unused portion.

2.4 Monitoring Vitamin Blood Levels

Blood vitamin concentrations should be monitored to ensure maintenance of adequate levels, particularly in patients receiving parenteral multivitamins as the only source of vitamins for long periods of time.

2.5 Drug Incompatibilities

- INFUVITE PEDIATRIC is not physically compatible with moderately alkaline solutions such as a sodium bicarbonate solution and other alkaline drugs such as acetazolamide sodium, aminophylline, ampicillin sodium, tetracycline HCl and chlorothiazide sodium.
- Folic acid is unstable in the presence of calcium salts such as calcium gluconate.
- Vitamin A and thiamine in INFUVITE PEDIATRIC may react with bisulfite solutions such as sodium bisulfite or vitamin K bisulfate.
- Do not add INFUVITE PEDIATRIC directly to intravenous fat emulsions.
- Consult appropriate references for listings of physical and chemical compatibility of solutions and drugs with the vitamin infusion. In such circumstances, admixture or Y-site administration with vitamin solutions should be avoided.

3 DOSAGE FORMS AND STRENGTHS

INFUVITE PEDIATRIC is an injection consisting of two vials labeled Vial 1 (40 mL Fill in 50 mL Vial) and Vial 2 (10 mL). The mixed solution (50 mL) will provide thirty-three 1.5 mL single doses, fifteen 3.25 mL single doses or ten 5 mL single doses. For the vitamin strengths, *see Dosage and Administration (2.2) and Description (11).*

4 CONTRAINDICATIONS

INFUVITE PEDIATRIC is contraindicated in patients who have:

- An existing hypervitaminosis, or
- A history of hypersensitivity due to any vitamins or excipients contained in this formulation.

5 WARNINGS AND PRECAUTIONS

5.1 Aluminum Toxicity

INFUVITE PEDIATRIC contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration in pediatric patients with renal impairment. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solution, which contain aluminum.

Patients with renal impairment, including premature neonates who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration. Consider periodic monitoring of aluminum levels with prolonged parenteral administration of INFUVITE PEDIATRIC.

5.2 Allergic Reactions to Thiamine

Allergic reactions such as urticaria, shortness of breath, wheezing and angioedema have been reported following intravenous administration of thiamine, which is found in INFUVITE PEDIATRIC. There have been rare reports of anaphylaxis following intravenous doses of thiamine. No fatal anaphylaxis associated with INFUVITE PEDIATRIC has been reported.

5.3. Hypervitaminosis A

Hypervitaminosis A, manifested by nausea, vomiting, headache, dizziness, blurred vision has been reported in patients with renal failure receiving 1.5 mg/day retinol and in patients with liver disease. Therefore, supplementation of renal failure patients and patients with liver disease with vitamin A, an ingredient found in INFUVITE PEDIATRIC, should be undertaken with caution [*See Use in Specific Populations (8.6, 8.7)*]. Blood levels of Vitamin A should be monitored periodically.

5.4 Vitamin K Antagonizes the Anticoagulant Action of Warfarin

Vitamin K, which is found in INFUVITE PEDIATRIC, antagonizes the anticoagulant action of warfarin. In patients who are on warfarin anticoagulant therapy receiving parenteral multivitamins such as with INFUVITE PEDIATRIC blood levels of prothrombin/INR should be periodically monitored to determine if dose of warfarin needs to be adjusted.

5.5 Interferes with Diagnosis of Megaloblastic Anemia

Avoid the use of INFUVITE PEDIATRIC in patients with suspected or diagnosed megaloblastic anemia prior to blood sampling for the detection of the folic acid and cyanocobalamin deficiencies. The folic acid and the cyanocobalamin in INFUVITE PEDIATRIC can mask serum deficits of folic acid and cyanocobalamin in these patients.

5.6 Potential to Develop Vitamin Deficiencies or Excesses

In patients receiving parenteral multivitamins such as with INFUVITE PEDIATRIC, blood concentration should be periodically monitored to determine if vitamin deficiencies or excesses are developing. INFUVITE PEDIATRIC may not correct long-standing specific vitamin deficiencies. The administration of additional doses of specific vitamins may be required [*see Dosage and Administration (2.2)*].

5.7 Interference with Urine Glucose Testing

INFUVITE PEDIATRIC contains vitamin C which is also known as ascorbic acid. Ascorbic acid in the urine may cause false negative urine glucose determinations.

5.8 Vitamin E Overdose in Infants Receiving Additional Vitamin E

Avoid additional oral or parental doses of vitamin E in infants. Daily dose of INFUVITE PEDIATRIC contains adequate concentrations of vitamin E required to achieve normal blood levels of vitamin E. Therefore, additional vitamin E supplementations of patients receiving INFUVITE PEDIATRIC may result in elevated blood concentrations of vitamin E and potential vitamin E toxicity in infants.

5.9 Risk of Low Vitamin A Levels

Vitamin A may adhere to plastic, resulting in lower vitamin A concentrations after administration of INFUVITE PEDIATRIC. Therefore, blood vitamin concentrations should be periodically monitored and the administration of additional therapeutic doses of vitamin A may be required, especially in low-birth weight infants.

5.10 Risk of E-Ferol Syndrome in Low-Birth Weight Infants

E-Ferol syndrome manifested by thrombocytopenia, renal dysfunction, hepatomegaly, cholestasis, ascites, hypotension and metabolic acidosis has been reported in low-birth weight infants following administration of polysorbates which are found in INFUVITE PEDIATRIC. No E-Ferol syndrome associated with INFUVITE PEDIATRIC has been reported.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling.

- Allergic reactions to thiamine [*see Warnings and Precautions (5.2)*].
- Hypervitaminosis A [*see Warnings and Precautions (5.3)*]

The following adverse reactions have been identified during postapproval use of the vitamins in INFUVITE PEDIATRIC. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Dermatologic: rash, erythema, pruritis

CNS: headache, dizziness, agitation, anxiety

Ophthalmic: diplopia

7 DRUG INTERACTIONS

7.1 Drug Interactions Affecting Co-administered Drugs

A number of interactions between vitamins and drugs have been reported. The following are examples of these types of interactions:

Warfarin: Vitamin K, a component of INFUVITE PEDIATRIC, antagonizes the anticoagulant action of warfarin. In patients who are co-administered warfarin and INFUVITE PEDIATRIC, blood levels of prothrombin/INR should be periodically monitored to determine if dose of warfarin needs to be adjusted.

Antibiotics: Thiamine, riboflavin, pyridoxine, niacinamide, and ascorbic acid decrease antibiotic activities of erythromycin, kanamycin, streptomycin, doxycycline, and lincomycin.

Bleomycin: Ascorbic acid and riboflavin inactivate bleomycin *in vitro*, thus the activity of bleomycin may be reduced.

Levodopa: Pyridoxine may increase the metabolism of levodopa (decrease blood levels of levodopa) and decrease its efficacy.

Phenytoin: Folic acid may increase phenytoin metabolism and lower the serum concentration of phenytoin resulting in increased seizure activity.

Methotrexate: Folic acid may decrease a patient's response to methotrexate therapy.

7.2 Drug Interactions Affecting Vitamin Levels

Hydralazine, Isoniazid:

Concomitant administration of hydralazine or isoniazid may increase pyridoxine requirements.

Phenytoin:

Phenytoin may decrease serum folic acid concentrations.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C.

INFUVITE PEDIATRIC has not been studied in pregnant women. Pregnant women should follow the U.S. recommended daily allowances for pregnancy because their vitamin requirements may exceed those of non-pregnant women. Animal reproduction studies have not been conducted with INFUVITE PEDIATRIC (multiple vitamins injection).

8.3 Nursing Mothers

INFUVITE PEDIATRIC has not been studied in nursing mothers. Lactating women may have vitamin requirements that exceed those of non-lactating women. Caution should be exercised when INFUVITE PEDIATRIC is administered to nursing mothers.

8.4 Pediatric Use

INFUVITE PEDIATRIC is approved for the prevention of vitamin deficiency in pediatric patients up to 11 years old receiving parenteral nutrition. INFUVITE PEDIATRIC has not been studied in pediatric patients older than 11 years.

INFUVITE PEDIATRIC contains aluminum that may be toxic for premature neonates. Aluminum levels should be monitored periodically during administration of INFUVITE PEDIATRIC to premature neonates [*see Warnings and Precautions (5.1)*].

Additional vitamin E supplementations of infants receiving INFUVITE PEDIATRIC may result in elevated blood concentrations of vitamin E and potential vitamin E toxicity [*see Warnings and Precautions (5.8)*].

E-Ferol syndrome has been reported in low-birth weight infants following administration of polysorbates which are found in INFUVITE PEDIATRIC. No E-Ferol syndrome associated with INFUVITE PEDIATRIC has been reported [*see Warnings and Precautions (5.10)*].

8.6 Renal Impairment

INFUVITE PEDIATRIC has not been studied in patients with renal impairment. Monitor renal function, calcium, phosphorus and vitamin A levels in patients with renal impairment [*see Warnings and Precautions (5.3)*].

8.7 Hepatic Impairment

INFUVITE PEDIATRIC has not been studied in patients with liver impairments. Monitor vitamin A levels in patients with liver disease [*see Warnings and Precautions (5.3)*].

10 OVERDOSAGE

Signs and symptoms of acute or chronic overdosage may be those of individual INFUVITE PEDIATRIC component toxicity. There is no clinical experience with INFUVITE PEDIATRIC overdosage.

11 DESCRIPTION

INFUVITE PEDIATRIC (multiple vitamins injection) is a sterile product consisting of 2 vials provided as a pharmacy bulk package for intravenous use:

(a) Vial 1 (40 mL Fill in 50 mL Vial); and
(b) Vial 2 (10 mL).

A pharmacy bulk package is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for intravenous infusion *[see Dosage and Administration (2.1)]*.

Each 4 mL of Vial 1 contains 10 vitamins (see Table 2).

Table 2: Active Ingredients in 4 mL of Vial 1

Active Ingredient	Quantity
Ascorbic acid (Vitamin C)	80 mg
Vitamin A* (as palmitate)	2,300 IU (equals 0.7 mg)
Vitamin D_3* (cholecalciferol)	400 IU (equals 10 mcg)
Thiamine (Vitamin B_1) (as the hydrochloride)	1.2 mg
Riboflavin (Vitamin B_2) (as riboflavin 5-phosphate sodium)	1.4 mg
Pyridoxine HCl (Vitamin B_6)	1 mg
Niacinamide	17 mg
Dexpanthenol (as *d*-pantothenyl alcohol)	5 mg
Vitamin E* (*dl*-α-tocopheryl acetate)	7 IU (equals 7 mg)
Vitamin K_1*	0.2 mg

*Polysorbate 80 is used to water solubilize the oil-soluble vitamins A, D, E, and K.

Inactive ingredients in Vial 1: 50 mg polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment, and water for injection.

Each 1 mL of Vial 2 contains 3 vitamins (see Table 3).

Table 3: Active Ingredients in 1 mL of Vial 2

Active Ingredient	Quantity
Folic acid	140 mcg
Biotin	20 mcg
Vitamin B_{12} (cyanocobalamin)	1 mcg

Inactive ingredients in Vial 2: 75 mg mannitol, citric acid and/or sodium citrate for pH adjustment and water for injection.

INFUVITE PEDIATRIC (multiple vitamins injection) makes available a combination of oil-soluble and water-soluble vitamins in an aqueous solution, formulated for incorporation into intravenous solutions. The liposoluble vitamins A, D,

E, and K have been solubilized in an aqueous medium with polysorbate 80, permitting intravenous administration of these vitamins.

INFUVITE PEDIATRIC contains no more than 30 mcg/L of aluminum (combined Vials 1 and 2).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity, and fertility studies have not been performed with INFUVITE PEDIATRIC.

16 HOW SUPPLIED/STORAGE AND HANDLING

INFUVITE PEDIATRIC (multiple vitamins injection) is supplied as a pharmacy bulk package available in boxes containing 2 vials – Vial 1 (40 mL Fill in 50 mL Vial) and Vial 2 (10 mL). Mix contents of Vial 2 with Vial 1 to provide thirty-three 1.5 mL single doses, fifteen 3.25 mL single doses or 10 single 5 mL doses *[see Dosage and Administration (2.2, 2.3)]*.

- NDC 54643-5647-0

Store at 2-8°C (36-46°F).

17 PATIENT COUNSELING INFORMATION

Instruct caregiver(s) and patients (if age appropriate) that:

- Caregivers should watch patients for signs of allergic reactions such as urticaria, shortness of breath, wheezing and angioedema, which have been reported following intravenous administration of thiamine.
- If patients have renal impairment caregivers should watch for and immediately report signs of hypervitaminosis A, manifested by nausea, vomiting, headache, dizziness, blurred vision.
- Instruct caregivers to report other adverse reactions that patients may experience such as rash, erythema, pruritus, headache, dizziness, agitation, anxiety, and diplopia.
- If patients who are on warfarin anticoagulant therapy, instruct caregivers that patients will be monitored periodically with blood prothrombin/ INR levels to determine if the dose of warfarin needs to be adjusted.
- Explain to caregivers the significance of periodic monitoring of blood vitamin concentrations to determine if vitamin deficiencies or excesses are developing and the need to monitor renal function, calcium, phosphorus, aluminum and vitamin A levels in patients with renal impairment.

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